IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC,

Plaintiff,

v.

SANDOZ, INC.,

Defendant.

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SANDOZ, INC.,

Counterclaim Plaintiff,

v.

ALLERGAN SALES, LLC AND ALLERGAN, INC.,

Counterclaim Defendants

Civil Action No. 2:15-cv-00347

Judge Rodney Gilstrap

**RESPONSE TO SANDOZ INC.'S MOTION FOR EARLIER TRIAL DATE IN LIGHT OF AGREED CONSOLIDATION WITH C.A. 2:12-CV-00207-JRG**

Sandoz's motion for an earlier trial date should be denied, as it has been Sandoz, not Allergan that has delayed the progress of this case. After losing at trial in August 2011 and on appeal in May 2013, Sandoz made a minor change to its label in June 2013 that it now alleges avoids infringement of claim 4 of the '149 patent. If Sandoz had fulfilled its obligations under the Hatch-Waxman Act and sent Allergan a new paragraph IV certification on its alleged "design around" at the time of its label amendment, this case could have been tried already. Instead, Sandoz gambled on an ill-fated Rule 60 motion in an attempt to short-circuit the process, and lost. Only after that loss on appeal did Sandoz finally send an updated paragraph IV certification, in January 2015, which triggered the start of this litigation.

Now, after it chose to delay triggering this litigation for 18 months, and having done nothing from the time the litigation was filed until now to move the case forward, Sandoz boldly accuses Allergan of delay and asks the Court to expedite this litigation. Sandoz's arguments are undermined by the factual record here, and its own dilatory conduct. Sandoz has had a chance to develop its new non-infringement defense for over two years without providing any discovery to Allergan, and now seeks to improperly fast-track the trial of this case to Allergan's disadvantage. Sandoz's motion provides no reason why, after it has delayed moving this case at every turn, this case now needs to move at breakneck speed.

Accordingly, for all these reasons and the reasons set forth below, Allegan respectfully requests that the Court deny Sandoz's motion and enter the proposed Docket Control Order[1] submitted by Allergan, which includes the trial and Markman hearing dates set by this Court.

## I. BACKGROUND

This case has more than six years of history, which will be summarized briefly below. Allergan first sued Sandoz in April 2009 after receiving Sandoz's first Paragraph IV letter, informing Allergan that Sandoz had filed an ANDA with the FDA for approval of a copycat version of Combigan® before expiration of the then Orange Book listed patents for that drug, the '149 and '976 patents. Sandoz's Paragraph IV letter asserted only that those patents were invalid and did not separately assert that the patents were not infringed. After receiving the Paragraph IV letter, Allergan promptly sued Sandoz and other Defendants under 35 U.S.C. § 271(e)(2), later adding the '463 and '258 patents to the suit.

[1] Despite multiple requests from Allergan, Sandoz provided no edits to or comments on Allergan's proposed Docket Control Order and refused to join any motion to enter the proposed Docket Control Order even in the event the Court denies Sandoz's motion.

Throughout that first litigation ("*Combigan I*"), the only non-infringement argument Sandoz ever raised related only to claims 1-3 of the '149 patent. Sandoz made no argument of non-infringement and submitted no expert reports on any other claim, including the claims of the '149, '976, and '258 patents at issue here. Then, on the first day of trial, Sandoz, along with the other Defendants, stipulated that the generic products described in their respective ANDAs "meet[] all of the limitations of claim 4 of U.S. Patent No. 7,030,149, claim 1 of U.S. Patent No. 7,320,976, claims 1-6 of U.S. Patent No. 7,323,463, and claims 1-9 of U.S. Patent No. 7,642,258 pursuant to 35 U.S.C. 271(e)(2)(A)," and therefore the products and the use of those products would infringe. The stipulation of infringement was not to "narrow the issues for trial" as Sandoz asserts in its opening brief, (Dkt. 28 at 5), but was consistent with the fact that Sandoz never had any non-infringement defense to any of the claims to be tried to begin with.

After a four-day bench trial in August 2011, Judge Ward found that Sandoz's proposed generic copy of Combigan® infringed all four patents-in-suit, relying on the stipulation of infringement, and that the patents had not been shown to be invalid. As required by 35 U.S.C. § 271(e)(4)(A), the Court then prohibited the approval of Sandoz's ANDAs until patent expiration and also enjoined Sandoz from "making, using, offering to sell, or selling" the "products described in [the ANDAs]" in the United States for the same period. Sandoz appealed the validity portion of that ruling, but did not appeal the District Court's finding of infringement.

In March 2012, after the District Court decision in *Combigan I* but while appeal of that decision was being briefed, U.S. Patent No. 8,133,890 ("the '890 patent") issued and was listed in the Orange Book. Allergan filed a second suit ("*Combigan II*") on April 13, 2012, asserting that Sandoz and other Defendants infringe the claims of the '890 patent. Later, Allergan amended its complaint to add U.S. Patent No. 8,354,409 ("the '409 patent") to the case. The

’890 and ’409 patents are continuations of the ’149 patent and share its expiration date—April 19, 2022.

On May 1, 2013, the Federal Circuit affirmed the District Court’s finding in *Combigan I* that claim 4 of the ’149 patent was not invalid, and held that “[t]he record firmly establishes that when brimonidine is dosed twice per day as opposed to three times per day, there is a loss of efficacy in the afternoon—the so called, afternoon trough. Sandoz has failed to point to evidence in the prior art that would allow us to conclude that the addition of timolol to brimonidine dosed twice per day would eliminate the afternoon trough issue.” *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1294 (Fed. Cir. 2013). The Court also determined that the claims of the ’463 patent, which broadly cover a fixed-combination formulation comprising 0.2% brimonidine tartrate and 0.5% timolol, were invalid as obvious. *Id.* at 1292-93. As to the ’976 and ’258 patents, the Court exercised its discretion and declined to rule on their validity, explaining that “[t]he ’258, ’976, and ’149 patents each expire on April 19, 2022. Because we conclude that claim 4 of the ’149 patent is not invalid, the Appellants will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the ’258 and ’976 patents.” *Id.* at 1294 n.2.

In a petition for rehearing, filed in June 2013, Sandoz primarily challenged the panel’s conclusion that it need not rule on the validity of the ’976 and ’258 patents, while also challenging the merits of the panel’s conclusion that claim 4 of the ’149 patent is not obvious. Sandoz also asserted for the first time that a ruling on the ’976 and ’258 patents was needed because Sandoz had amended its pending ANDA. This amendment, the specifics of which Sandoz declined to disclose to the panel or to Allergan at that time, was apparently made at some

point in June 2013, over four years after Sandoz's ANDA was filed, almost two years after entry of the judgment and injunction, and after the Federal Circuit's panel decision.

After the panel denied rehearing, Sandoz's pattern of delay relevant to this case then began. Sandoz did not send Allergan a new paragraph IV certification on its alleged "design around." Instead, on September 20, 2013, Sandoz filed a Rule 60(b)(5) motion to modify the injunction in *Combigan I*, hoping to undo its prior stipulation of infringement and the injunction against approval of its ANDA.

In its opposition to Sandoz's Rule 60 motion, filed in October 2013, Allergan explained that the proper method to litigate Sandoz's alleged "design-around" was through the filing of a new Paragraph IV certification and a new lawsuit, as the Hatch-Waxman Act envisions. (C.A. No. 2:09-cv-097, Dkt. 292 at 10; *see also* Dkt. 14, Counterclaims ¶ 36.) On December 3, 2013, this Court properly denied Sandoz's request, finding that, under controlling Fifth Circuit precedent, Rule 60(b)(5) does not permit the relief Sandoz is requesting in the first place, let alone require the Court to re-assess infringement, which Sandoz admitted, and validity, which Sandoz lost, simply because Sandoz decided to amend its ANDA after losing. *See Allergan, Inc. v. Sandoz Inc.*, No. 2:09-cv-097, 2013 WL 6253669 (E.D. Tex. Dec. 3, 2013). On December 6, 2013, Sandoz appealed this Court's denial of its Rule 60 motion to the Federal Circuit. Sandoz still did not send Allergan a new paragraph IV certification.

While Sandoz's Rule 60 Motion was pending, on October 23, 2013, Allergan moved to stay the *Combigan II* litigation in light of the Federal Circuit's decision in *Combigan I*. At the hearing on the motion to stay on December 3, 2013, counsel for Sandoz represented to this Court that "[w]e're going to do everything we can to expedite that appeal [of the decision on Sandoz's Rule 60 motion] and move it forward." (C.A. No. 2:12-cv-207, Dec. 3, 2013 Hearing Tr. at

12:1-2.) (*See also id.* at 19:9-10.) ("We're going to do everything we can to move it along. We think it will be definitely short of a year."). Despite those representations to this Court, during the course of that appeal Sandoz requested and received more than 100 days of extensions to file its briefing and rehearing petition. Sandoz's appeal was unsuccessful, with the Federal Circuit affirming this Court's ruling in December 2014 and denying rehearing in April 2015.

After this Court's denial of Sandoz's Rule 60 motion, but while appeal of that decision was pending, U.S. Patent No. 8,748,425 ("the '425 patent") issued in June 2014 and was promptly listed in the Orange Book. The '425 patent is a continuation of the '149 patent and shares its expiration date—April 19, 2022.

In January 2015, more than six months after the '425 patent was listed in the Orange Book and more than eighteen months after Sandoz's label amendment, Sandoz finally did what it was supposed to do if it wished to litigate its alleged design-around—it sent Allergan a new Paragraph IV certification. (Dkt 1 ¶ 33.) In that letter, Sandoz informed Allergan that it had amended its ANDA to include a Paragraph IV certification to the '425 patent, and also amended its certifications as to the '149, '976, and '258 patents. (Dkt. 1 ¶ 35.)

Allergan promptly filed this lawsuit within 45 days of receiving Sandoz's letter to preserve Allergan's rights under the Hatch-Waxman Act, including its rights to a 30-month stay on approval of Sandoz's amended ANDA.

## II. SANDOZ'S MOTION FOR A NEW TRIAL DATE SHOULD BE DENIED BECAUSE SANDOZ'S PROPOSAL WILL PREJUDICE ALLERGAN AND PROVIDES AN UNFAIR TACTIAL ADVANTAGE TO SANDOZ

### A. Any Delay in this Case Is of Sandoz's Own Making

Sandoz amended its ANDA in June 2013. If it had sent Allergan a Paragraph IV certification at that time, as it should have done under the Hatch-Waxman Act, this case could

have been tried by now. Sandoz chose not to do so, and now, after delaying for years, it attempts to blame Allergan for delay. Sandoz's accusation is wholly without merit.

Throughout the entirety of *Combigan I*, Sandoz never raised any argument about non-infringement of claim 4 of the '149 patent. Instead, Sandoz, presumably on the advice of its counsel, chose to stipulate to infringement of claim 4 of the '149 patent and all the asserted claims of the '976, '258, and '463 patents. At the time of this stipulation, Sandoz was fully aware that, if it was unable to demonstrate by clear and convincing evidence that every single asserted claim was invalid, the Court would order—as it did—that the FDA is prohibited from approving their ANDAs until the patents-in-suit expired under 35 U.S.C. § 271(e)(4)(A).

After its loss in *Combigan I* at trial and on appeal, Sandoz undertook a new litigation strategy and asserted for the first time in its petition for rehearing to the Federal Circuit—without disclosing any details to Allergan or the Court—that Sandoz had amended its ANDA in an effort to avoid infringement of the '149 patent. And, after the Federal Circuit denied its petition for rehearing, Sandoz cobbled together a brand new non-infringement defense along with a brand new claim construction argument based its amended ANDA, still hoping for a do-over of its loss in *Combigan I*. But rather than present these arguments and changes formally through an amended Paragraph IV notification to Allergan under the Hatch-Waxman Act, Sandoz chose to file a Rule 60(b)(5) motion in this Court, arguing that it had "designed around" claim 4 of the '149 patent by amending its label to delete the word "glaucoma" and asked this Court to undo summarily the result of five years of litigation in *Combigan I*.

Sandoz is wrong to suggest that it had no avenue of relief other than a Rule 60 motion and ignores the avenues available to it under the Hatch-Waxman Act. (Dkt. 28 at 10.) Indeed, Allergan has consistently told Sandoz that if Sandoz really wished to litigate its supposed

"design-around," it was free to file a new Paragraph IV certification allowing Allergan to file another lawsuit for infringement on the supposed design-around as the Hatch-Waxman Act envisions. (Dkt. 14, Counterclaims ¶ 36.) Sandoz made a conscious choice not to provide a revised Paragraph IV certification to Allergan at that time.

The contempt standard in the lone case cited by Sandoz in its opening brief to justify its failed Rule 60 strategy is not relevant to the framework of the Hatch-Waxman Act. *See TiVo Inc. v. Echostar Corp.*, 646 F.3d 869 (Fed. Cir. 2011). Sandoz suggests that *TiVo* provides that courts will generally contemplate motions to modify or clarify injunctions. But Sandoz ignores the context of that statement in *TiVo*. The Court in *TiVo* explained that, where an injunction is vague and a defendant seeks clarification of the terms rather than risking a contempt proceeding, a motion to modify or clarify the injunction may be appropriate. *TiVo*, 646 F.3d at 886. In its Rule 60 motion, Sandoz did not argue that the injunction barring the approval of its ANDA was vague. And *TiVo* certainly contains no endorsement of the procedure Sandoz followed—stipulating to infringement, losing on validity, and waiting until two years after entry of judgment to assert a design-around that supposedly no longer infringes. Notably, Sandoz raised these same arguments on appeal of the Rule 60 motion to the Federal Circuit. The Federal Circuit rejected all of them, without opinion.

Until now, Sandoz has been in no rush to litigate is new non-infringement position and it provides no excuse for not sending a revised Paragraph IV certification to Allergan in June 2013 after the label amendment, in October 2013 after Allergan asserted that a Paragraph IV letter was the proper procedure, in December 2013 after this Court denied the Rule 60 motion, or in June 2014, when the '425 patent issued and was listed in the Orange Book. And Sandoz's current sense of urgency is also belied by the extensions totaling nearly 120 days that Sandoz sought and

received during the appeal of its Rule 60 motion despite Sandoz's representations to this Court that Sandoz was going to expedite that appeal.

Having chosen to wait for more than eighteen months after amending its ANDA, and more than six months after the '425 patent was listed in the Orange Book to send Allergan its revised Paragraph IV certification, Sandoz should not now be heard to complain that it is Allergan that "wants to delay generic competition by delaying the present case."

### B. The Expedited Trial Proposed by Sandoz Will Prejudice Allergan and Provides an Unfair Tactical Advantage to Sandoz

Sandoz has now had more than two years to develop its new non-infringement and claim construction arguments related to its label amendment. At the same time, it has denied any discovery on those issues to Allergan beyond the label amendment itself. Yet Sandoz now improperly seeks to fast track this trial to Allergan's detriment.

Sandoz's self-servingly asserts that "the new issues in this case do not require extensive new discovery" and that "any remaining claim constructions will be straightforward." But until Allergan filed this litigation, Allergan had no vehicle to conduct that discovery or to learn what those issues are and will be. Indeed, during the depositions of Sandoz's witnesses in the *Combigan II* litigation, Sandoz blocked any inquiry about its amended label. (C.A. No. 2:09-cv-97 TJW, Dkt. 292, Ex. 10 at 201:6-13, 203:12-204:9, 206:4-207:9, 209:18-212:5, 216:13-218:7, 219:16-22, 220:3-221:11.) And it was only recently that Sandoz finally produced the remainder of the FDA correspondence related to its design-around, despite possessing it since January of this year. (Reichel Decl. Ex. 1[2].) Moreover, there is an additional patent in this case, the '425 patent, which while similar to the '890 patent, likely presents different issues for discovery.

[2] "Reichel Decl." refers to the declaration of Deanna J. Reichel filed concurrently herewith.

As to the merits, the issues raised in this case by Sandoz, as framed by Sandoz, appear quite complex. As Allergan understands it, Sandoz asserts that by removing the word "glaucoma" from the label, while leaving the words "ocular hypertension" in place, it avoids infringement because "[o]phthalmologists in the United States do not prescribe 0.2% brimonidine three times per day to patients with ocular hypertension. Patients with ocular hypertension do not take 0.2% brimonidine three times per day. Therefore, no ocular hypertension patients switch from a three-times-a day dosage of 0.2% brimonidine to a twice-a-day dosage of brimonidine/timolol fixed combination." (Dkt. 14, Counterclaims ¶ 28.)

As an initial matter, this brand new non-infringement argument appears to depend on a construction of the claim that requires that individual patients must be switched from brimonidine three times daily to twice daily dosing in Combigan®. Sandoz did not advance this claim construction position in the *Combigan I* litigation though Sandoz certainly could have raised it and relied on it[3], even in the absence of the label amendment. Moreover, as Allergan understands it, Sandoz intends to support this position with multiple experts, which Allergan intends to dispute. Indeed, during the parties' negotiations over their Proposed Discovery Order, Sandoz requested that each side be allowed to designate six testifying experts instead of the four proposed by Allergan. (Reichel Decl. Ex. 2 (at email dated Aug. 11, 2015).) And, in incorrectly asserting that the parties took "limited discovery" in the *Combigan II* case due to the "related nature" of the *Combigan I* and *II* litigations, Sandoz fails to point out that the parties took a total of eighteen depositions in the *Combigan II* case, including 11 depositions of fact witnesses, the majority of whom had been deposed before in the *Combigan I* case.

[3] Allergan does not intend to waive any rights that Sandoz may be precluded from advancing this claim construction position. Allergan disagrees with Sandoz's position, as Allergan currently understands it.

In short, this case appears to be like most patent cases – presenting significant issues of law for the Court, and fact for the trier of fact. While certainly there has been some "water under the bridge," that does not mean that the case does not require due consideration. Given this, it appears that Sandoz now seeks to leverage improperly its two year head-start in developing its new non-infringement and claim construction arguments to gain an unfair tactical advantage over Allergan, which is apparent in its proposal to the Court for a different schedule. Although Sandoz was in no rush to serve its invalidity and non-infringement contentions any earlier than the requirements of P.R. 3-8 (c) and (d), Sandoz's proposed schedule requires Allergan to provide Sandoz with Allergan's infringement contentions on September 11, 2015, more than two weeks before they are due pursuant to P.R. 3-8(e). And Sandoz's proposed schedule sets the Markman hearing less than four months from now, in December 2015, with opening expert reports due a month later. This Court should reject Sandoz's ploy.

Lastly, there is the issue of prejudice. There is no prejudice to Sandoz from being required to proceed in an orderly fashion consistent with the Court's currently scheduled trial and Markman dates of February 6, 2017 and March 2, 2016, respectively, while the prejudice to Allergan is plain. Sandoz had its first chance to litigate over a generic version of COMBIGAN and lost. It then chose to wait more than 18 months to send its amended Paragraph IV letter and should not be heard now to complain about speed. And while the Hatch-Waxman Act exists in part to speed generics to market, it also strikes a balance and provides for the protection of innovator patent rights. Sandoz should not be able to profit from its strategic gamesmanship to Allergan's detriment.

## III. CONCLUSION

For all the reasons set forth above, Allergan respectfully requests that this Court deny Sandoz's motion for an earlier trial date.

Dated: August 31, 2015

Respectfully Submitted,

*/s/ Deanna J. Reichel*

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## CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email, on this 31st day of August, 2015.

*/s/ Deanna J. Reichel*
Deanna J. Reichel